REMARKS

FORMAL MATTERS:

Claims 1-54 and 61 were previously canceled without prejudice. Claims 55-60 and 62-72 were examined. Claims 55, 56, 58, 59, 65, and 70-72 were rejected. Claims 57, 60, 62, 65, 66, 68 and 69 were objected to as being dependent upon a rejected base claim but were otherwise indicated to be allowable if rewritten in independent form. Claims 63, 64, and 67 were indicated to be allowable.

By this Amendment, Claims 55 and 70 have been amended. Support for these amendments is found throughout the specification, in particular at Paragraphs 0046, 0052 and 0069 to 0072.

Claims 55-60 and 62-72 remain pending after entry of the amendments set forth herein.

REJECTIONS UNDER §112, ¶2

Claims 70-71 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In making the rejection, the Examiner asserts that it is not clear where the aggregation enhancer is located in the system recited in independent claim 55.

Claim 70 has been amended to specify that the calcium ion solution comprises at least one aggregation enhancer. The Applicants respectfully submit that this rejection has been adequately addressed and request that the rejection be withdrawn.

REJECTIONS UNDER §103(a)

Claims 55-56, 58-59, 65, and 72 were rejected under 35 U.S.C. 103(a) as being unpatentable over either Coller (U.S. Patent No. 5,854,005) or Vogler et al. (U.S. Patent No. 5,246,666) in view of Sanz (U.S. Patent No. 3,692,487). The Applicants respectfully traverse the rejection.

As amended, claim 55 is directed to a coagulation test evaluation system which features a control composition container. The container includes plasma aggregatable particles located within a first compartment and a solution of calcium ions located within the second compartment and is configured to allow the particles and calcium ions to be combined within the container. Further, the addition of

plasma, results in a control composition that mimics the action of whole blood when applied or introduced to a coagulation test system such as a test strip.

Coller fails to disclose, teach or suggest such a control composition container. In fact, Coller fails to disclose a composition for use as a control. Coller discloses a method of determining the level of residual unblocked glycoprotein IIb/IIIa receptors. The agglutinization of small polymeric beads coated with a glycoprotein IIb/IIIa ligand such as fibrinogen results when the beads are contacted with whole blood containing platelets with glycoprotein IIb/IIIa receptors that are not blocked. As such, Coller does not teach or suggest a control composition but instead provides an assay for diagnosis. Therefore, Coller does not provide a control composition and therefore, fails to provide a container for the control composition.

With respect to Vogler, the reference fails to disclose, teach or suggest the control composition container as provided in the present invention. Vogler discloses a blood collection tube having an additive that has a wettable surface region and a nonwettable surface region. The additive is able to both initiate the clotting cascade as well as becoming part of the clot, which is able to be removed upon centrifugation. However, Vogler does not use the additive as a control composition and in fact, makes no mention of a control composition at all. Therefore, the blood collection tube is not the equivalent of the Applicants control composition container but instead, merely a test tube for clotting blood.

Sanz fails to disclose a control composition container. Sanz is directed to a two piece tubular capsule for conducting coagulation tests on blood. The tubular capsule features a testing capsule for storing a blood sample and also includes compartments for the necessary solutions for determining the coagulation time. As such, the tubular capsule is specifically used to conduct the coagulation tests for diagnostic purposes but does not provide a control composition. Therefore, the container in Sanz is a test container and not a control container.

Because the cited combination of references fails to teach or suggest a control composition container, it is respectfully submitted that claim 55 and the claims that depend therefrom are not obvious under 35 U.S.C. § 103(a) over Coller or Vogler in view of Sanz and that this rejection may therefore be withdrawn.

Claims 70 and 71 were rejected under 35 U.S.C. 103(a) as being unpatentable over either Coller or Vogler et al. in view of Sanz as applied to claims 55-56, 58-59, 65, and 72 above, and further in view of Lewis et al. (U.S. Patent No. 4,847,209).

For at least the reasons set forth above, with respect to the rejections of claims 55-56, 58-59, 65, and 72, these rejections have also been traversed. The additional references fail to teach or suggest the missing elements of Coller, Vogler, and Sanz.

CONCLUSION

The Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number LIFE-043DIV.

Respectfully submitted,
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